

REMARKS

Claims 1-28 are pending and under examination. Claims 29-62 stand withdrawn from consideration for being directed to a non-elected invention. Claims 1, 8 and 14 have been amended as set forth above in the Listing of Claims. Claim 1 has been amended to incorporate claim 4, which has been cancelled. In particular, claim 8 has been amended correct grammatical and typographical errors. Claim 14 has been amended to correctly reflect the lack of antecedent basis for "angiotensin receptor" in claim 1. Claim 15 has been amended to incorporate claim 16, which has been cancelled. The amendments do not introduce any new matter and entry of the amendments is respectfully requested. New claims 63-86 have been added herein.

Newly added base claims 63, 64, 85 and 86 are directed to acceleration of the cell cycle of 10%, 25%, 50% and 75%, respectively. The new base claims are supported throughout the application as filed, for example, at page 16, lines 8-11. The newly added dependent claims are similarly supported throughout the application as filed, for example, by original claims 2-23. No new matter is added by the amendments and entry is respectfully requested. Upon entry of the amendments, claims 1-3 and 5-15, 17-28 and 63-86 will be pending and under examination.

Regarding the Claim Objections

Claim 8 has been amended to address the objections set forth at page 3 of the Office Action. Accordingly, withdrawal of the rejection is respectfully requested.

Regarding 35 U.S.C. §112, Second Paragraph

The rejection of claim 14 under 35 U.S.C. §112, Second Paragraph, as allegedly indefinite is traversed. The rejection has been rendered moot by the amendment to claim 14 and removal of the rejection is respectfully requested.

Regarding 35 U.S.C. §112, First Paragraph

The objection to the specification and corresponding rejection of claims 1-29 under 35 U.C. 112 , first paragraph, for allegedly lacking an enabling disclosure is respectfully rejected.

The Office Action alleges at page 3 that the specification , while being enabling for an *in vitro* method of acceleration of the cell cycle in fibroblasts using radio frequency radiation, *in*

vitro method of activation of a cell cycle regulator, a signal transduction protein , a transcription factor, a DNA synthesis protein and a receptor in fibroblasts keratinocytes using radio frequency radiation , does not reasonably provide enablement for an the corresponding *in vivo* methods.

To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without **undue** experimentation. Accordingly, we have held that the specification must provide sufficient teaching such that one skilled in the art could make and use the full scope of the invention without undue experimentation. *CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1338 (Fed. Cir. 2003); *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997); “The key word is ‘undue,’ not experimentation.” *Wands*, 858 F.2d at 737 (citation omitted). That is, the specification need only teach those aspects of the invention that one skilled in the art could not figure out without undue experimentation. See, e.g., *Nat'l Recovery Techs.*, 166 F.3d at 1196 (“The scope of enablement . . . is that which is disclosed in the specification plus the scope of what would be known to one of ordinary skill in the art without undue experimentation.”); *Wands*, 858 F.2d at 736-37 (“Enablement is not precluded by the necessity for some experimentation such as routine screening.”). Furthermore, “[w]hether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations.” *Wands*, 858 F.2d at 737.

The Office organized its enablement analysis around the Wands factors. *In re Wands*, 858 F.2d 731, 736-37 (Fed. Cir. 1988). The *Wands* factors are “**illustrative**, not mandatory,” *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1213 (Fed. Cir. 1991). More importantly, the Office Action, at page 3, explicitly concedes enablement of the *in vitro* methods by the specification, which discloses extensive *in vitro* examples. Therefore, **the burden is on the Office to produce evidence that the correlation between *in vitro* and *in vivo* results would not be accepted by the skilled person. If the art is such that a particular model is recognized as correlating to a specific condition, then it should be accepted as correlating unless the examiner has evidence that the model does not correlate.** Even with such evidence, the examiner must weigh the evidence for and against correlation and decide whether one skilled in the art would accept the model as reasonably correlating to the condition. *In re Brana*, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995) (reversing the PTO decision based on finding that *in vitro* data did not support *in vivo* applications).

The Office Action cites various scientific publications as evidence that the *in vivo* applications lack enablement. However, contrary to the Office's assertion, the cited publications

do not suggest lack of enablement. Rather, in view of the Office's concession that the *in vitro* embodiments are properly enabled, these references confirm that the enabled *in vitro* working examples are recognized by those skilled in the art as correlating to *in vivo* conditions. Otter et al. report that the impact of electromagenetic energy on a cell is achieved through coupling to the cell interior via transmembrane receptors. *See abstract.* This observation is consistent and provides support for the enablement provided to support the claimed invention. The Simko and Mattson reference similarly supports enablement of the claimed invention by reporting EMF effects on various processes, including the cell cycle. Aaron et al. reports similar findings, in particular, that EMF upregulate various intracellular mechanisms. The Simko and Mattson reference cited in the present Office Action clearly confirms that *in vitro* results are accepted in the art as reasonably correlating to *in vivo* results. In particular, this reference uses *in vitro* data regarding cellular changes in response to electromagnetic field exposure as a basis to draw a variety of conclusion about *in vivo* effects. Unless the Office produces particular evidence to the contrary, the acknowledgement that *in vitro* methods are enabled, should be accepted as evidence for the enablement of the *in vivo* embodiments of the invention.

The teachings in the specification contain detailed extensive working examples that demonstrate the enablement of the claimed methods. As described in Example I, treated cells were demonstrated to enter the S phase of the cell cycle on average, 8 hours before untreated controls. The specification discloses results that demonstrate that RF acts as an exogenous, non-molecular mitogen that induces the release of soluble factors via a transduction pathway that includes ERK-1, and that the resulting soluble factor release re-stimulates the mitogenic signaling pathway as demonstrated by the second phase of ERK-1 activation. *See Figure 3.* The specification further discloses the induction of a large number of the genes, which were studied in a programmed manner. The working example further shows that the genes that showed the earliest response included genes that encode extracellular matrix proteins and signal transduction, while genes involved in regulation of the cell cycle and DNA synthesis were transcribed at later time points, corresponding to the influx of signal from the extracellular membrane through the cytoplasm, and into the nucleus. *See Example II and Figures 6 and 7.*

In view of the extensive teachings and working examples; the Office's acknowledgement that the *in vitro* methods are enabled and the evidence those skilled in the art accepted the correlation between *in vitro* and *in vivo* results for the claimed methods, it is respectfully submitted that the enablement rejection is not properly supported. Accordingly, Applicants respectfully request withdrawal of the objection to the specification and removal of the

corresponding rejection of claims 1-29 under 35 U. C. 112 , first paragraph, for allegedly lacking an enabling disclosure.

Regarding 35 U.S.C. § 102

When lack of novelty is based on a printed publication that is asserted to describe the same invention, a finding of anticipation requires that the publication describe all of the elements of the claims. *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1349, 48 U.S.P.Q.2d 1225, (Fed. Cir. 1998) (quoting *Shearing v. Iolab Corp.*, 975 F.2d 1541, 1544-45, 24 U.S.P.Q.2d 1133, 1136 (Fed. Cir. 1992)). To establish a *prima facie* case of anticipation, the Office must show that the single reference cited as anticipatory art describes all the elements of the claimed invention.

George et al., U. S. Patent No. 6,334,069

The rejection of claims 1-3, 5-13, 15-18 and 20-24 under 35 U.S.C. §102(b) as being anticipated by George et al (U. S. Patent No. 6,334;069, 12/25/2001) is respectfully traversed. This rejection has been rendered moot by the amendment to claim 1. Accordingly, removal of the rejection is respectfully requested.

George et al., U. S. Patent No. 6,353,763

The rejection of claims 1-3, 5-13, 15-18 and 20-24 under 35 U.S.C. §102(a) as being anticipated by George et al (U. S. Patent No. 6,353,763, 3/5/2002). This rejection has been rendered moot by the amendment to claim 1. Accordingly, removal of the rejection is respectfully requested.

The rejection of claims 1-3, 5-13, 15-18 and 20-24 under 35 U.S.C. §102(e) as being anticipated by George et al (U. S. Patent No. 6,353,763, 3/5/2002) is respectfully traversed. This rejection has been rendered moot by the amendment to claim 1. Accordingly, removal of the rejection is respectfully requested.

George et al., U. S. Patent No. 7,024,239

The rejection of claims 1-3, 5-13, 15-18 and 20-24 under 35 U.S.C. §102(e) as being anticipated by George et al (U. S. Patent No. 7,024,239 , filed 11/20/2001) is respectfully traversed. This rejection has been rendered moot by the amendment to claim 1. Accordingly, removal of the rejection is respectfully requested.

Lenhardt and Ochs U. S. Patent No. 6,250,255

The rejection of claim 27 under 35 U. C. 102(b) as being anticipated by Lenhardt and Ochs (U. S Patent No. 6,250,255 , 6/26/2001). The hair cell receptors referred to in the '255

Patent are distinct from the receptors of the claimed invention. Hair cells have structures called stereocilia, which sense sounds by bending back and forth, converting mechanical vibrations into electrical, or neural, signals that are then passed to the brain through the auditory nerve. These **sensory** receptors are distinct from a receptors of the claimed invention, which is defined as a protein that binds to a molecule and transduces a signal that alters cell function. Accordingly, withdrawal of the rejection of claim27 is rejected under 35 U. C. 102(b) as being anticipated by Lenhardt and Ochs (U. S Patent No. 6,250,255 , 6/26/2001) is respectfully requested.

Yarosh, U. S. Patent No. 5,352,458

The rejection of claim 26 under 35 U.S.C. §102(b) as being anticipated by Yarosh (U.S. Patent No, 5,352,458) is respectfully traversed. The Office, other than making the assertion that DNA repair enzymes read on DNA synthesis peptides, has not made a showing that this is correct. DNA repair enzymes and DNA synthesis proteins are distinct groups of proteins. Accordingly, withdrawal of the rejection of claim 26 under 35 U.S.C. §102(b) as being anticipated by Yarosh (U.S. Patent No, 5,352,458) is respectfully requested.

Blumberg, U. S. Patent Application Publication No. US2003/0073888

The rejection of claims 15, 20 and 23-27 are rejected under 35 U.S.C. §102(e) as being anticipated by Blumberg (U. S. Patent Application Publication No. US2003/0073888 filed 09/06/2001) is respectfully traversed. This rejection has been rendered moot by the amendment to claim 15 to incorporate claim 16, which was not rejected over this reference. Accordingly, removal of the rejection is respectfully requested.

Wang et al., Cancer Res., 56: 2510-2514(1997)

The rejection of claims 15 and 20 are rejected under 35 U.S.C. §102(b) as being anticipated by Wang et al (Cancer Res. , Vol. 56. pages 2510-2514) is respectfully traversed. This rejection has been rendered moot by the amendment to claim 15 to incorporate claim 16, which was not rejected over this reference. Accordingly, removal of the rejection is respectfully requested.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 502624 and please credit any excess fees to such deposit account.



Respectfully submitted,

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A handwritten signature in black ink that appears to read "Astrid R. Spain".

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